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10/809,217	03/25/2004	Shoji Miyazaki	55220/844	6571

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EXAMINER
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NOGUEROLA, ALEXANDER STEPHAN

ART UNIT	PAPER NUMBER
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1795

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10/17/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/809,217	<b>Applicant(s)</b> MIYAZAKI ET AL.	
	<b>Examiner</b> ALEX NOGUEROLA	<b>Art Unit</b> 1795	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 3/25/2004 (preliminary amendment).
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 45-65 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 45-65 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☒ Certified copies of the priority documents have been received in Application No. 09/889,243.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |  |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)                                    |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____   |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application                          |
| Paper No(s)/Mail Date <u>8/15/2008</u> .   | 6) <input checked="" type="checkbox"/> Other: <u>IDS of 4/16/2007 and IDS of 3/25/04</u> . |



## DETAILED ACTION

### *Double Patenting*

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

### *Double Patenting Rejections based on U.S. Patent No. 6,875,327 B1*

2. Claims 45 and 47 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 10 of U.S. Patent No. 6,875,327 B1 (“Miyazaki”). Although the conflicting claims are not identical, they are not patentably

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distinct from each other because claim 10 of Miyazaki meets all of the limitations of claims 45 and 47 of the instant application.

3. Claim 46 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 11 of U.S. Patent No. 6,875,327 B1 ("Miyazaki"). Claim 45, from which claim 46 depends, has been addressed above. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 11 of Miyazaki meets the additional limitation of claim 46 of the instant application.

4. Claim 49 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over the combination of claims 3 and 10 of U.S. Patent No. 6,875,327 B1 ("Miyazaki"). Claim 45, from which claim 49 depends, has been addressed above. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 3 of Miyazaki meets the additional limitations of claim 49 of the instant application.

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5. Claim 50 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over the combination of claims 4 and 10 of U.S. Patent No. 6,875,327 B1 ("Miyazaki"). Claim 45, from which claim 50 depends, has been addressed above. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 4 of Miyazaki meets the additional limitations of claim 50 of the instant application.

6. Claim 51 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over the combination of claims 5 and 10 of U.S. Patent No. 6,875,327 B1 ("Miyazaki"). Claim 47, from which claim 51 depends, has been addressed above. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 5 of Miyazaki meets the additional limitations of claim 51 of the instant application.

7. Claim 52 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over the combination of claims 6 and 10 of U.S. Patent

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No. 6,875,327 B1 ("Miyazaki"). Claim 51, from which claim 52 depends, has been addressed above. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 6 of Miyazaki meets the additional limitations of claim 52 of the instant application.

8. Claim 53 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over the combination of claims 7 and 10 of U.S. Patent No. 6,875,327 B1 ("Miyazaki"). Claim 45, from which claim 53 depends, has been addressed above. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 7 of Miyazaki meets the additional limitations of claim 53 of the instant application.

9. Claim 54 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over the combination of claims 8 and 10 of U.S. Patent No. 6,875,327 B1 ("Miyazaki"). Claim 53, from which claim 54 depends, has been addressed above. Although the conflicting claims are not identical, they are not

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patentably distinct from each other because claim 8 of Miyazaki meets the additional limitations of claim 54 of the instant application.

10. Claim 55 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over the combination of claims 9 and 10 of U.S. Patent No. 6,875,327 B1 ("Miyazaki"). Claim 45, from which claim 55 depends, has been addressed above. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 9 of Miyazaki meets the additional limitations of claim 55 of the instant application.

11. Claim 56 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over the combination of claims 12 and 10 of U.S. Patent No. 6,875,327 B1 ("Miyazaki"). Claim 45, from which claim 56 depends, has been addressed above. Although the conflicting claims are not identical, they are not



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patentably distinct from each other because claim 12 of Miyazaki meets the additional limitations of claim 56 of the instant application.

12. Claim 57 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over the combination of claims 13 and 10 of U.S. Patent No. 6,875,327 B1 ("Miyazaki"). Claim 56, from which claim 57 depends, has been addressed above. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 13 of Miyazaki meets the additional limitations of claim 57 of the instant application.

13. Claims 58 and 59 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over the combination of claims 14 and 10 of U.S. Patent No. 6,875,327 B1 ("Miyazaki"). Claim 45, from which claim 58 depends, has been addressed above. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 14 of Miyazaki meets the additional limitations of claim 59 of the instant application.

14. Claim 60 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over the combination of claims 14, 15, and 10 of U.S. Patent No. 6,875,327 B1 ("Miyazaki"). Claim 45, from which claim 60 depends, has been addressed above. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 14 and 15 together of Miyazaki meet the additional limitations of claim 60 of the instant application.

15. Claim 61 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over the combination of claims 14, 16, and 10 of U.S. Patent No. 6,875,327 B1 ("Miyazaki"). Claim 60, from which claim 61 depends, has been addressed above. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 16 of Miyazaki meets the additional limitations of claim 61 of the instant application.

16. Claim 62 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over the combination of claims 18 and 10 of U.S. Patent No. 6,875,327 B1 ("Miyazaki"). Claim 45, from which claim 62 depends, has been addressed above. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 18 of Miyazaki meets the additional limitations of claim 62 of the instant application.

17. Claim 63 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over the combination of claims 19 and 10 of U.S. Patent No. 6,875,327 B1 ("Miyazaki"). Claim 45, from which claim 63 depends, has been addressed above. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 19 of Miyazaki meets the additional limitations of claim 63 of the instant application.

18. Claim 64 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over the combination of claims 19 and 10 of U.S. Patent No. 6,875,327 B1 ("Miyazaki"). Claim 45, from which claim 64 depends, has been addressed above. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 19 of Miyazaki meets the additional limitations of claim 64 of the instant application.

19. Claim 65 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over the combination of claims 20 and 10 of U.S. Patent No. 6,875,327 B1 ("Miyazaki"). Claim 45, from which claim 65 depends, has been addressed above. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 20 of Miyazaki meets the additional limitations of claim 65 of the instant application.

Double Patenting Rejections based on U.S. Patent Application No. 10/809,240

20. Claims 45, 56, and 58 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 47 of copending Application No. 10/809,240 ("Miyazaki II") in view of Winarta et al. US 6,287,451 B1 ("Winarta"). Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 47 of Miyazaki II meets all of the limitations of claims 45 and 56 of the instant application except for the reagent being formed by dripping a reagent and having the second slits (third slits in Miyazaki II) provided around a position where the reagent is dripped, which are obvious.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

As for the reagent being formed by dripping a reagent, this is a product-by-process limitation that does not patentably distinguish the reagent of the claims of Miyazaki II from Applicant's reagent.

As for the second slits being provided around a position where the reagent is dripped this is met by Winarta.

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Winarta discloses biosensor for quantifying a substrate included in a sample liquid (col. 01:01-20) comprising:

a first insulating support (20) and a second insulating support (50);

an electrode part comprising at least a working electrode and a counter electrode (col. 10:36-40 – note that since there is not a separate counter electrode one with ordinary skill in the art would understand that the reference electrode also functions as a counter electrode);

a specimen supply path (112) for introducing the sample liquid to the electrode part (col. 10:63 – col. 11:02); and

a reagent layer employed for quantifying the substrate included in the sample liquid (col. 10:41-53 and col. 09:14-26),

where the electrode part, the specimen supply path, and the reagent layer are situated between the first insulating support and the second insulating support

(Figure 2),

the specimen supply path being provided on the electrode part, and the reagent layer being provided on the electrode part in the specimen supply path, respectively (Figure 2 and col. 10:41-43),

the electrode part being dividedly formed by a first type of slits provided on an electrical conductive layer which is formed on the whole or part of an internal surface of

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one or both of the first insulating support and the second insulating support (Figure 2 and col. 07:58-61),

the reagent layer is formed by dripping a reagent (this is a product-by-process limitation that does not patentably distinguish the dispensed reagent of Winarta, which was probably “dripped”, from Applicant’s reagent), and

a second type of slits (the three angled segments of slit 28 at the front end of the biosensor shown in Figure 2 can be construed as three second type of slits as they are not for forming electrodes, but means to “avoid potential static problems which could give rise to a noisy signal” – col. 07:63 to col. 08:01) is provided around a position where the reagent is dripped (Figure 2).

It would have been obvious to one with ordinary skill in the art at the time of the invention to have the second slits provided around a position where the reagent is dripped as taught by Winarta in the invention of Miyazaki II because as taught by Winarta this will form means to “avoid potential static problems which could give rise to a noisy signal” – col. 07:63 to col. 08:01.

21. Claim 46 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 47 of copending Application No. 10/809,240 (“Miyazaki II”) in view of Winarta. Claim 45, from which claim 46 depends, has been addressed above. Miyazaki as modified by Winarta only discloses linear slits.

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See Figure 2 in WInarta. However, to make the second type of slits arc-shaped is just a mere arbitrary change in shape, unless Applicant shows that the slit shape is significant.

See MPEP 2144.04.IV.B.

This is a provisional obviousness-type double patenting rejection.

22. Claim 47 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 49 of copending Application No.

10/809,240 ("Miyazaki II") in view of WInarta. Claim 45, from which claim 47 depends, has been addressed above. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 49 of Miyazaki II meets the additional limitation of claim 47 of the instant application.

This is a provisional obviousness-type double patenting rejection.

23. Claim 48 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 50 of copending Application No.

10/809,240 ("Miyazaki II") in view of WInarta. Claim 45, from which claim 48 depends, has been addressed above. Although the conflicting claims are not identical, they are



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not patentably distinct from each other because claim 50 of Miyazaki II meets the additional limitation of claim 48 of the instant application.

This is a provisional obviousness-type double patenting rejection.

24. Claim 49 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 51 of copending Application No. 10/809,240 ("Miyazaki II") in view of WInarta. Claim 45, from which claim 49 depends, has been addressed above. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 51 of Miyazaki II meets the additional limitation of claim 49 of the instant application.

This is a provisional obviousness-type double patenting rejection.

25. Claim 50 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 52 of copending Application No. 10/809,240 ("Miyazaki II") in view of WInarta. Claim 45, from which claim 50 depends, has been addressed above. Although the conflicting claims are not identical, they are

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not patentably distinct from each other because claim 52 of Miyazaki II meets the additional limitation of claim 50 of the instant application.

This is a provisional obviousness-type double patenting rejection.

26. Claim 51 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 53 of copending Application No. 10/809,240 ("Miyazaki II") in view of WInarta. Claim 47, from which claim 51 depends, has been addressed above. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 53 of Miyazaki II meets the additional limitation of claim 51 of the instant application.

This is a provisional obviousness-type double patenting rejection.

27. Claim 52 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 54 of copending Application No.

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10/809,240 ("Miyazaki II") in view of WInarta. Claim 51, from which claim 52 depends, has been addressed above. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 54 of Miyazaki II meets the additional limitation of claim 52 of the instant application.

This is a provisional obviousness-type double patenting rejection.

28. Claim 53 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 55 of copending Application No. 10/809,240 ("Miyazaki II") in view of WInarta. Claim 53, from which claim 54 depends, has been addressed above. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 55 of Miyazaki II meets the additional limitation of claim 53 of the instant application.

This is a provisional obviousness-type double patenting rejection.

29. Claim 54 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 56 of copending Application No. 10/809,240 ("Miyazaki II") in view of WInarta. Claim 53, from which claim 54 depends, has been addressed above. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 56 of Miyazaki II meets the additional limitation of claim 54 of the instant application.

This is a provisional obviousness-type double patenting rejection.

30. Claim 55 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 57 of copending Application No. 10/809,240 ("Miyazaki II") in view of WInarta. Claim 45, from which claim 55 depends, has been addressed above. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 57 of Miyazaki II meets the additional limitation of claim 55 of the instant application.

This is a provisional obviousness-type double patenting rejection.

31. Claim 57 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 48 of copending Application No. 10/809,240 ("Miyazaki II") in view of WInarta. Claim 56, from which claim 57 depends, has been addressed above. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 48 of Miyazaki II meets the additional limitation of claim 57 of the instant application.

This is a provisional obviousness-type double patenting rejection.

32. Claim 59 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over the combination of claims 47 and 58 of copending Application No. 10/809,240 ("Miyazaki II") in view of WInarta. Claim 58, from which claim 59 depends, has been addressed above. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 58 of Miyazaki II meets the additional limitation of claim 59 of the instant application.

This is a provisional obviousness-type double patenting rejection

33. Claim 60 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over the combination of claims 47 and 60 of copending Application No. 10/809,240 ("Miyazaki II") in view of WInarta. Claim 45, from which claim 60 depends, has been addressed above. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 60 of Miyazaki II meets the additional limitation of claim 60 of the instant application.

This is a provisional obviousness-type double patenting rejection

34. Claim 61 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over the combination of claims 47 and 61 of copending Application No. 10/809,240 ("Miyazaki II") in view of WInarta. Claim 60, from which claim 61 depends, has been addressed above. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 61 of Miyazaki II meets the additional limitation of claim 61 of the instant application.

This is a provisional obviousness-type double patenting rejection

35. Claim 62 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over the combination of claims 47 and 62 of copending Application No. 10/809,240 ("Miyazaki II") in view of WInarta. Claim 45, from which claim 62 depends, has been addressed above. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 62 of Miyazaki II meets the additional limitation of claim 62 of the instant application.

This is a provisional obviousness-type double patenting rejection

36. Claims 63 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over the combination of claims 47 and 63 of copending Application No. 10/809,240 ("Miyazaki II") in view of WInarta. Claim 45, from which claim 63 depends, has been addressed above. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 63 of Miyazaki II meets the additional limitation of claim 63 of the instant application.

This is a provisional obviousness-type double patenting rejection

37. Claims 64 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over the combination of claims 47 and 64 of copending Application No. 10/809,240 ("Miyazaki II") in view of WInarta. Claim 45, from which claim 64 depends, has been addressed above. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 64 of Miyazaki II meets the additional limitation of claim 64 of the instant application.

This is a provisional obviousness-type double patenting rejection

38. Claims 65 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over the combination of claims 47 and 65 of copending Application No. 10/809,240 ("Miyazaki II") in view of WInarta. Claim 45, from which claim 65 depends, has been addressed above. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 65 of Miyazaki II meets the additional limitation of claim 65 of the instant application.

This is a provisional obviousness-type double patenting rejection



***Claim Rejections - 35 USC § 102***

39. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

40. Claims 45, 53-55, and 62-65 are rejected under 35 U.S.C. 102(e) as being anticipated by Winarta et al. US 6,287,451 B1 (“Winarta”).

Addressing claim 45, Winarta discloses biosensor for quantifying a substrate included in a sample liquid (col. 01:01-20) comprising:

a first insulating support (20) and a second insulating support (50);

an electrode part comprising at least a working electrode and a counter

electrode (col. 10:36-40 – note that since there is not a separate counter electrode one with ordinary skill in the art would understand that the reference electrode also functions as a counter electrode);

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a specimen supply path (112) for introducing the sample liquid to the electrode part (col. 10:63 – col. 11:02); and

a reagent layer employed for quantifying the substrate included in the sample liquid (col. 10:41-53 and col. 09:14-26),

where the electrode part, the specimen supply path, and the reagent layer are situated between the first insulating support and the second insulating support

(Figure 2),

the specimen supply path being provided on the electrode part, and the reagent layer being provided on the electrode part in the specimen supply path, respectively (Figure 2 and col. 10:41-43),

the electrode part being dividedly formed by a first type of slits provided on an electrical conductive layer which is formed on the whole or part of an internal surface of one or both of the first insulating support and the second insulating support (Figure 2 and col. 07:58-61),

the reagent layer is formed by dripping a reagent (this is a product-by-process limitation that does not patentably distinguish the dispensed reagent of Winarta, which was probably “dripped”, from Applicant’s reagent), and

a second type of slits (the three angled segments of slit 28 at the front end of the biosensor shown in Figure 2 can be construed as three second type of slits as they are not for forming electrodes, but means to “avoid potential static problems which could

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give rise to a noisy signal” – col. 07:63 to col. 08:01) is provided around a position where the reagent is dripped (Figure 2).

Addressing claim 53, for the additional limitations of this claim see Figure 2 in Winarta and note spacer 40.

Addressing claim 54, for the additional limitation of this claim see Figures 1 and 2; col. 11:09-11; and col. 11:39-41 .

Addressing claim 55, for the additional limitation of this claim note element 52 in Figure 2.

Addressing claims 62-65, for the additional limitations of these claims see col. 07:44-51; col. 08:26-52; and col. 09:14-40.

41. Claims 46, 47, 49, and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Winarta et al. US 6,287,451 B1 (“Winarta”) in view of Ikeda et al. US 5,582,697 (“Ikeda”).

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Winarta discloses biosensor for quantifying a substrate included in a sample liquid (col. 01:01-20) comprising:

a first insulating support (20) and a second insulating support (50);

an electrode part comprising at least a working electrode and a counter electrode (col. 10:36-40 – note that since there is not a separate counter electrode one with ordinary skill in the art would understand that the reference electrode also functions as a counter electrode);

a specimen supply path (112) for introducing the sample liquid to the electrode part (col. 10:63 – col. 11:02); and

a reagent layer employed for quantifying the substrate included in the sample liquid (col. 10:41-53 and col. 09:14-26),

where the electrode part, the specimen supply path, and the reagent layer are situated between the first insulating support and the second insulating support

(Figure 2),

the specimen supply path being provided on the electrode part, and the reagent layer being provided on the electrode part in the specimen supply path, respectively (Figure 2 and col. 10:41-43),

the electrode part being dividedly formed by a first type of slits provided on an electrical conductive layer which is formed on the whole or part of an internal surface of

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one or both of the first insulating support and the second insulating support (Figure 2 and col. 07:58-61),

the reagent layer is formed by dripping a reagent (this is a product-by-process limitation that does not patentably distinguish the dispensed reagent of Winarta, which was probably “dripped”, from Applicant’s reagent), and

a second type of slits (the three angled segments of slit 28 at the front end of the biosensor shown in Figure 2 can be construed as three second type of slits as they are not for forming electrodes, but means to “avoid potential static problems which could give rise to a noisy signal” – col. 07:63 to col. 08:01) is provided around a position where the reagent is dripped (Figure 2).

Addressing claim 46, Winarta only discloses linear slits. See Figure 2 in Winarta. However, to make the second type of slits arc-shaped is just a mere arbitrary change in shape, unless Applicant shows that the slit shape is significant. See MPEP 2144.04.IV.B.

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Addressing claim 47, Winarta does not disclose the electrode part further comprising a detecting electrode; however, Winarta does disclose providing a third electrode, W2, that could also function as a detecting electrode. As shown by Ikeda a third electrode located at the end of a capillary channel in a biosensor test strip could be used as a detecting electrode in addition to alternatively being involved in the actual sample measurement (abstract and Figure 1).

Addressing claim 49, for the additional limitations of this claim see Figure 2 and col. 07:58-61 in Winarta. Recall that Ikeda is only cited for showing that an electrode at the end of a capillary channel in a biosensor test strip could also be used as a detecting electrode.

For claim 51 note that Winarta discloses that the cutouts for the working electrodes have the same area and that the cutout for the counter/reference electrode may be the same or larger than that for the each working electrode. See col. 04:48-54. Since electrode W2 is being construed as a detecting electrode (actually a dual purpose pseudo working electrode/ detecting electrodes) the sum of the area for electrode "R" (the counter/reference electrode) and the area of W2 (detecting /pseudo working electrode) will necessarily be greater than that of the W1 (the working electrode).

42. Claim 50 is rejected under 35 U.S.C. 103(a) as being unpatentable over Winarta in view of Kawaguri et al. US 5,171,689 ("Kawaguri").

Winarta discloses biosensor for quantifying a substrate included in a sample liquid (col. 01:01-20) comprising:

a first insulating support (20) and a second insulating support (50);

an electrode part comprising at least a working electrode and a counter electrode (col. 10:36-40 – note that since there is not a separate counter electrode one with ordinary skill in the art would understand that the reference electrode also functions as a counter electrode);

a specimen supply path (112) for introducing the sample liquid to the electrode part (col. 10:63 – col. 11:02); and

a reagent layer employed for quantifying the substrate included in the sample liquid (col. 10:41-53 and col. 09:14-26),

where the electrode part, the specimen supply path, and the reagent layer are situated between the first insulating support and the second insulating support

(Figure 2),

the specimen supply path being provided on the electrode part, and the reagent layer being provided on the electrode part in the specimen supply path, respectively (Figure 2 and col. 10:41-43),

the electrode part being dividedly formed by a first type of slits provided on an electrical conductive layer which is formed on the whole or part of an internal surface of one or both of the first insulating support and the second insulating support (Figure 2 and col. 07:58-61),

the reagent layer is formed by dripping a reagent (this is a product-by-process limitation that does not patentably distinguish the dispensed reagent of Winarta, which was probably “dripped”, from Applicant’s reagent), and

a second type of slits (the three angled segments of slit 28 at the front end of the biosensor shown in Figure 2 can be construed as three second type of slits as they are not for forming electrodes, but means to “avoid potential static problems which could give rise to a noisy signal” – col. 07:63 to col. 08:01) is provided around a position where the reagent is dripped (Figure 2).

Winarta discloses that the cutouts exposing the working electrodes may be the same or different than the size of the cutout exposing the reference electrode. See col. 04:50-53. Alternatively, although not needed to meet the claim, Kawaguri teaches that making the area of a counter/reference electrode larger than that of the working electrodes in a solid-state biosensor will stabilize the potential. See col. 04:06-21.



43. Claims 56-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Winarta in view of Kawanaka et al. US 6,599,406 B1 ("Kawanaka").

Addressing claim 56, Winarta discloses biosensor for quantifying a substrate included in a sample liquid (col. 01:01-20) comprising:

a first insulating support (20) and a second insulating support (50);

an electrode part comprising at least a working electrode and a counter electrode (col. 10:36-40 – note that since there is not a separate counter electrode one with ordinary skill in the art would understand that the reference electrode also functions as a counter electrode);

a specimen supply path (112) for introducing the sample liquid to the electrode part (col. 10:63 – col. 11:02); and

a reagent layer employed for quantifying the substrate included in the sample liquid (col. 10:41-53 and col. 09:14-26),

where the electrode part, the specimen supply path, and the reagent layer are situated between the first insulating support and the second insulating support

(Figure 2),

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the specimen supply path being provided on the electrode part, and the reagent layer being provided on the electrode part in the specimen supply path, respectively (Figure 2 and col. 10:41-43),

the electrode part being dividedly formed by a first type of slits provided on an electrical conductive layer which is formed on the whole or part of an internal surface of one or both of the first insulating support and the second insulating support (Figure 2 and col. 07:58-61),

the reagent layer is formed by dripping a reagent (this is a product-by-process limitation that does not patentably distinguish the dispensed reagent of Winarta, which was probably “dripped”, from Applicant’s reagent), and

a second type of slits (the three angled segments of slit 28 at the front end of the biosensor shown in Figure 2 can be construed as three second type of slits as they are not for forming electrodes, but means to “avoid potential static problems which could give rise to a noisy signal” – col. 07:63 to col. 08:01) is provided around a position where the reagent is dripped (Figure 2).

Winarta does not disclose providing a third type of slits for dividing the electrical conductive layer to define an area of the electrode part.

Kawanaka discloses a concentration measuring apparatus, test strip for the concentration measuring apparatus, biosensor system and method for forming terminal on the test strip. The test strip is substantially planar and comprises laminated layers and a type of slits for dividing the electrical conductive layer to define an area of the

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electrode part. See the title, abstract, Figures 33, 34, 8, 9, 20, 22, 24, and 28-32. It would have been obvious to one with ordinary skill in the art at the time of the invention to provide a type of slits for dividing the electrical conductive layer to define an area of the electrode part as taught by Kawanaka in the invention of WInarta, which would be a third type of slits, because as taught by Kawanaka then the information regarding the test strip, such as the particular analyte the test strip is configured to measure and the appropriate potential to be used during the measurement, can be conveyed to the measuring apparatus. See col. 02:45 – col. 05:07.

Addressing claim 57, for the additional limitations of this claim see Figure 2 in WInarta and Figures 8, 9, 20, 22, 24, and 28-32 in Kawanaka.

Addressing claims 58 and 59, Winarta discloses biosensor for quantifying a substrate included in a sample liquid (col. 01:01-20) comprising:

- a first insulating support (20) and a second insulating support (50);

- an electrode part comprising at least a working electrode and a counter

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electrode (col. 10:36-40 – note that since there is not a separate counter electrode one with ordinary skill in the art would understand that the reference electrode also functions as a counter electrode);

a specimen supply path (112) for introducing the sample liquid to the electrode part (col. 10:63 – col. 11:02); and

a reagent layer employed for quantifying the substrate included in the sample liquid (col. 10:41-53 and col. 09:14-26),

where the electrode part, the specimen supply path, and the reagent layer are situated between the first insulating support and the second insulating support

(Figure 2),

the specimen supply path being provided on the electrode part, and the reagent layer being provided on the electrode part in the specimen supply path, respectively (Figure 2 and col. 10:41-43),

the electrode part being dividedly formed by a first type of slits provided on an electrical conductive layer which is formed on the whole or part of an internal surface of one or both of the first insulating support and the second insulating support (Figure 2 and col. 07:58-61),

the reagent layer is formed by dripping a reagent (this is a product-by-process limitation that does not patentably distinguish the dispensed reagent of Winarta, which was probably “dripped”, from Applicant’s reagent), and

a second type of slits (the three angled segments of slit 28 at the front end of the biosensor shown in Figure 2 can be construed as three second type of slits as they are not for forming electrodes, but means to “avoid potential static problems which could give rise to a noisy signal” – col. 07:63 to col. 08:01) is provided around a position where the reagent is dripped (Figure 2).

Winarta does not disclose providing in the biosensor information of correction data generated for each production lot of the biosensor, which correspond to characteristics concerning output of an electrical change resulting from a reaction between the sample liquid and the reagent layer and can be discriminated by a measuring device employing the biosensor.

Kawanaka discloses a concentration measuring apparatus, test strip for the concentration measuring apparatus, biosensor system and method for forming terminal on the test strip. The test strip is substantially planar and comprises laminated layers and a type of slits for dividing the electrical conductive layer to define an area of the electrode part, which would be a fourth type of slits (the third type of slit conveys information on what analyte the biosensor is configured to detect - see rejection of claim 56 above). See the title, abstract, Figures 33, 34, 8, 9, 20, 22, 24, and 28-32. It would have been obvious to one with ordinary skill in the art at the time of the invention to provide a type of slits for dividing the electrical conductive layer to define an area of the

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electrode part as taught by Kawanaka in the invention of Winarta because as taught by Kawanaka then the information of correction data regarding the test strip as claimed (calibration data) can be conveyed to the measuring apparatus. See col. 05:44 – col. 06:08.

Addressing claim 60, Winarta discloses biosensor for quantifying a substrate included in a sample liquid (col. 01:01-20) comprising:

a first insulating support (20) and a second insulating support (50);

an electrode part comprising at least a working electrode and a counter electrode (col. 10:36-40 – note that since there is not a separate counter electrode one with ordinary skill in the art would understand that the reference electrode also functions as a counter electrode);

a specimen supply path (112) for introducing the sample liquid to the electrode part (col. 10:63 – col. 11:02); and

a reagent layer employed for quantifying the substrate included in the sample liquid (col. 10:41-53 and col. 09:14-26),

where the electrode part, the specimen supply path, and the reagent layer are situated between the first insulating support and the second insulating support

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(Figure 2),

the specimen supply path being provided on the electrode part, and the reagent layer being provided on the electrode part in the specimen supply path, respectively (Figure 2 and col. 10:41-43),

the electrode part being dividedly formed by a first type of slits provided on an electrical conductive layer which is formed on the whole or part of an internal surface of one or both of the first insulating support and the second insulating support (Figure 2 and col. 07:58-61),

the reagent layer is formed by dripping a reagent (this is a product-by-process limitation that does not patentably distinguish the dispensed reagent of Winarta, which was probably “dripped”, from Applicant’s reagent), and

a second type of slits (the three angled segments of slit 28 at the front end of the biosensor shown in Figure 2 can be construed as three second type of slits as they are not for forming electrodes, but means to “avoid potential static problems which could give rise to a noisy signal” – col. 07:63 to col. 08:01) is provided around a position where the reagent is dripped (Figure 2).

Winarta does not disclose providing a third type of slits and a fourth type of slits formed by processing the electrical conductive layer by a laser.

Kawanaka discloses a concentration measuring apparatus, test strip for the concentration measuring apparatus, biosensor system and method for forming terminal

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on the test strip. The test strip is substantially planar and comprises laminated layers and a type of slits for dividing the electrical conductive layer to define an area of the electrode part, which would be a third type of slits and a fourth type of slits (the third type of slit conveys information on what analyte the biosensor is configured to detect - see rejection of claim 56 above). See the title, abstract, Figures 33, 34, 8, 9, 20, 22, 24, and 28-32. It would have been obvious to one with ordinary skill in the art at the time of the invention to provide a third type of slits for dividing the electrical conductive layer to define an area of the electrode part and a fourth type of slits as taught by Kawanaka in the invention of Winarta because as taught by Kawanaka then the information of correction data regarding the test strip as claimed can be conveyed to the measuring apparatus. For example, the third slits can indicate the particular analyte the test strip is configured to measure and the fourth slits can indicate calibration date. See col. 02:45 – col. 05:07 and col. 05:44 – col. 06:08.

As for the slits being formed using a laser, this is a product-by-process limitation that does not further patentably limit the slits. In any event Winarta discloses forming slits in the electrically conductive material using a laser. See col. 04:15-30 and col. 07:54-63.



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44. Claim 61 is rejected under 35 U.S.C. 103(a) as being unpatentable over WInarta in view of Kawanaka as applied to claims 56-60 above, and further in view of Fujiwara et al. US 6,004,441 ("Fujiwara").

WInarta as modified by Kawanaka does not appear to mention the possible widths of the slits; however, as noted in the rejection of claim 60 WInarata does disclose using a laser to form the slits.

Fujiwara discloses making slits in a metal film to make electrodes or a test strip type biosensor. The slits are made using a laser and be 70 microns (=0.07mm) in width. See the abstract and col. 02:52-59. In light of Fujiwara Applicant's claimed slit width range of 0.005 mm to 0.3 mm is just a matter of scaling the biosensor to the expected volume range of sample, by , for example, making smaller more closely spaced electrodes for smaller expected sample volumes.

45. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALEX NOGUEROLA whose telephone number is (571) 272-1343. The examiner can normally be reached on M-F 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, NAM NGUYEN can be reached on (571) 272-1342. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/Alex Noguera/  
Primary Examiner, Art Unit 1795  
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